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K002293
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510(k) SUMMARY AS REQUIRED BY SECTION 807.92(C)

Submitted by: Mrs. Mitsuko Yoneyama
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Date Submitted: July 25, 2000

Device Identification:

Trade Name: 3D Motor-Driven Coarse Manipulator MM-188NE
Common Name: Coarse Manipulator
Classification Name: Assisted Reproduction Micromanipulators and
Microinjectors (21 CFR, 884.6150)

Predicate Device:

3D Motor-Driven Coarse Manipulator MM-188NE is substantially equivalent to predicate 3D Manual Coarse Manipulator MN-188NE.

Device Description:

The 3D Motor-Driven Coarse Manipulator MM-188NE helps coarse positioning of a microtool under the microscope. The MM-188NE is a motor-driven coarse manipulator and it consists of three components, Drive Unit, Control Unit, and Power Transformer. The Drive Unit consists of three sliders and each slider moves in different direction in the respective straight line, X-, Y-, and Z-axis, controlled by the Control Unit. The MM-188NE is mounted on the microscope and the definition of X-, Y-, and Z-axis is as follows:

- X-axis for X-axis Unit (right-left with relation to the microscope)
- Y-axis for Y-axis Unit (front-rear with relation to the microscope)
- Z-axis for Z-axis Unit (up-down with relation to the microscope)

The 3D Motor-Driven Coarse Manipulator MM-188NE is a component part of the micromanipulator system.

A micromanipulator system for the Assisted Reproduction technique, ICSI, requires:

- 1 unit of manipulator mounting adaptor;
- 2 units of coarse manipulator (for coarse positioning) (2 units of the MM-188NE);
- 2 units of fine micromanipulator (for fine positioning);
- 2 units of the joint unit (for holding the pipette holder);
- 2 units of microinjector (one for holding pipette and one for injecting pipette);
- 1 holding pipette
- 1 injecting pipette

Examples of the role the MM-188NE plays in the system would be:

- coarse positioning of the micropipette into the field of view under the microscope
- coarse positioning of the holding pipette
- coarse positioning of the injecting pipette

Intended Use:

The 3D Motor-Driven Coarse Manipulator MM-188NE helps coarse positioning of a microtool under the microscope.

Substantial Equivalence:

Narishige Co., Inc. claims 3D Motor-Driven Coarse Manipulator MM-188NE as substantially equivalent to 3D Manual Coarse Manipulator MN-188NE, Premarket Notification 510(k) Number: K001130.

Technological Characteristic:

The 3D Motor-Driven Coarse Manipulator MM-188NE is designed compact allowing ample space around the microscope stage.

The MM-188NE is designed for one hand easy operation. Each Control is located close together within reach without much moving the hand.

The operating range of each control is summarized in the table below

Control Unit	Drive Unit
Joystick (X-axis Control) :	X-axis Unit:
Maximum Operating Range	22mm
Joystick (Y-axis Control):	Y-axis Unit:
Maximum Operating Range	22mm
UP/DOWN Button (Z-axis Control):	Z-axis Unit:
Maximum Operating Range	22mm

Safety Feature:

For electrical safety, the cover for the Fuse Box and Voltage Selecting Unit cannot be opened unless the Power Cord is unplugged from the Power Transformer.

Safety Requirements:

The 3D Motor-Driven Coarse Manipulator MM-188NE conforms to CE Marking of EN61326: 1998 for EMC, Electromagnetic Compatibility and BS EN 61010-1:1993 Incorporating Amendment 1 for LVD, Low Voltage Directive.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Re: K002293
3D Motor-Driven Coarse Manipulator MM-188NE
Dated: July 25, 2000
Received: July 27, 2000
Regulatory Class: II
21 CFR 884.6150/Procode: 85 MQJ

Dear Mrs. Yoneyama:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. ~~Failure to comply with the GMP regulation may result in regulatory action.~~ In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation ~~Control provisions, or other~~ Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

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510(k) Number (if known): K002293

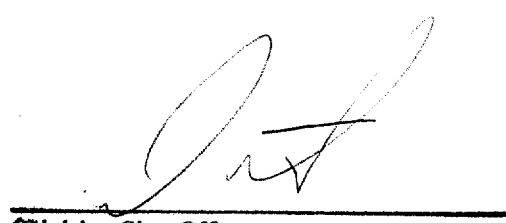
Device Name: 3D Motor-Driven Coarse Manipulator MM-188NE

Indications For Use:

The 3D Motor-Driven Coarse Manipulator MM-188NE helps coarse positioning of a microtool under the microscope and is used in assisted reproduction procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002293

(Optional Format 3-10-98)

Prescription Use ✓
(Per 21 CFR 801.109)